

**CERTIFICATE OF ELECTRONIC TRANSMISSION**

I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent and Trademark Office on 23 August 2007.

/Lynne M. Milliot/

Lynne M. Milliot

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

**Michael G. Kahn et al.**

Application No.: **09/584,936**

Confirmation No.: **5001**

Filed: **31 May 2000**

Title: **CLINICAL TRIALS MANAGEMENT  
SYSTEM AND METHOD**

Group Art Unit: **3626**

Examiner: **Lena Najarian**

**CUSTOMER NO. 22470**

**MAIL STOP AF**

Commissioner of Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION OF INVENTOR MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

I, MICHAEL MISCHKE-REEDS, declare as follows:

1. I am one of the inventors named in the above-identified patent application.

With this Declaration, I provide documentary evidence that the invention of the above-identified patent application was conceived prior to September 10, 1999, and that we worked diligently toward a reduction to practice from a date prior to September 10, 1999, until after May 31, 2000.

2. I was an employee of FastTrack Systems, Inc. before, during and after the period September 10, 1999 through May 31, 2000.

**Conception**

3. Claim 1, as currently pending in the above-identified patent application, calls roughly for a computer readable medium carrying a machine readable database identifying: (1) patient eligibility criteria for a clinical trial protocol; and (2) a plurality of workflow tasks for the clinical trial protocol. The workflow tasks are to include either (a) a post-enrollment instruction to have a specified test performed on the patient, or (b) a post-enrollment instruction to have a specified CRF completed for the patient.

4. We conceived of such a product well prior to September 10, 1999, and as evidence of this I attach (1) a document dated prior to September 10, 1999 entitled "FASTTRACK Systems, Inc. Execuctive (sic) Summary" (attached hereto as Exhibit A), and (2) screen shots from two non-functional demos developed prior to September 10, 1999 at the request of FastTrack Systems (attached hereto as Exhibits B-H).

5. Exhibit A is an Executive Summary prepared by Michael Kahn and others at FastTrack Systems. The date of the document is not in the document itself, but the name of the document on disk is "FT Executive Smry \*\*\*\*\*.doc", where I have replaced the actual date with asterisks. The actual date included in the name of the document is prior to September 10, 1999.

6. Pages 2-3 of Exhibit A recite:

The heart of FASTTRACK's technology is the Intelligent Clinical Protocol (ICP). The clinical protocol is the foundation of every trial and largely determines the time, cost and ultimate success or failure of the trial. All parts of a trial, including recruitment, treatment, data requirements, trial management and reporting, flow from detailed specifications contained in the protocol. FASTTRACK believes that a system driven by the fundamental protocol provides the best solution for improving the trial process.

The ICP begins with a protocol authoring tool that exploits detailed knowledge bases such as trial design templates, historical and competing clinical trials, actual medical procedure costs, anonymized patient clinical summaries, FDA and

European regulatory requirements, preclinical pharmacokinetic and pharmacodynamic models and statistical parameters to assist the pharmaceutical medical director optimize study design and model all aspects of the clinical development process. FASTTRACK software automatically translates the protocol into an intelligent electronic Case Report Form (eCRF) to be transmitted electronically to the physicians performing trials. Anticipating the rapid growth of electronic medical records, the eCRF will automatically screen the physician's or institution's current patient records to determine trial eligibility.

Following enrollment, FASTTRACK protocol-directed workflow management software will generate appropriate role-specific task lists to ensure that the physician, nurses and other staff execute the trial tasks as specified in the protocol. Finally, FASTTRACK standard point of care data collection devices to ensure that all required data is captured in real time and is automatically 'reality & quality checked' while the patient is in the physician's exam room.

\*\*\*

Additional direct benefits to the study sponsors include: rapid analysis of interim study results, immediate implementation of any mid-study protocol modifications, near real-time monitoring of patient accrual and other project milestones, and point-of-service data validation and quality assurance. Direct benefits to study locations include: rapid patient accrual using automated screening tools, automatic protocol modifications without manual intervention, automated workflow and task lists for improved study productivity and throughput, and electronic data capture eliminating paper piles. The use of automated processes will eliminate many oversight steps which currently are done manually. Removing the manual tasks will significantly reduce direct labor costs, travel expenses, and time-to-database-lockdown.

7. On information and belief, the ICP referred to in this excerpt was to be a database that would include numerous facets of a clinical trial protocol. The database was to drive numerous automated process tools for both pre- and post-enrollment processes defined by the protocol. The mentions in the last paragraph of the excerpt, concerning "immediate implementation of any mid-study protocol modifications," "rapid patient accrual using automated screening tools," "automatic protocol modifications without manual intervention," and "automated workflow and task lists," all corroborate my recollection that the automated tools would be driven by the ICP database, such that a change in the content of the database would automatically modify the operation of all dependent tools without manual intervention. In order to accomplish this, the database

was to include all the necessary data for driving these tools. Such data was to include "patient eligibility criteria", so as to drive the mentioned automated patient screening tools, as well as "post-enrollment instructions to have a specified test performed on a patient", so as to drive the "automated workflow and task lists."

8. My recollection that the database was to include "patient eligibility criteria" is corroborated further by the statement in the above excerpt that "FASTTRACK software automatically translates the protocol into an intelligent electronic Case Report Form (eCRF) to ... automatically screen the physician's or institution's current patient records to determine trial eligibility."

9. My recollection that the database was also to include "post-enrollment instructions to have a specified test performed on a patient", is corroborated further by the statement in the above excerpt that "Following enrollment, FASTTRACK protocol-directed workflow management software will generate appropriate role-specific task lists to ensure that the physician, nurses and other staff execute the trial tasks as specified in the protocol."

10. My recollection that the database was also to include "post-enrollment instructions to have a specified CRF completed for a patient," is corroborated by the statement in the above excerpt that "Finally, FASTTRACK standard point of care data collection devices to ensure that all required data is captured in real time and is automatically 'reality & quality checked' while the patient is in the physician's exam room."

11. Exhibit B. Exhibit B is a screen shot of the directory listing of a folder on a FastTrack Systems CD-ROM, setting forth the last-modified date of two software

applications, SITE.exe and SPONSOR.exe. The dates themselves have been redacted for purposes of this submission, but they are prior to September 10, 1999.

12. SITE.exe was a non-functional demo developed at the request of FastTrack Systems by a company called MONKEYmedia. The software presented a mock-up of some of the features that we expected that a study site's tool would support when executed.

13. SPONSOR.exe was another a non-functional demo developed at the request of FastTrack Systems by MONKEYmedia. SPONSOR.exe presented a mock-up of some of the features that we expected that a study sponsor's tool would support when executed.

14. Exhibits C-E are screen shots generated by the SITE.exe program when executed. Exhibit C illustrates the initial screen. It can be seen that the tool was to allow study site physicians to view information regarding patients, protocols, accrual information, and on-study tasks, among other things.

15. Exhibit D is a screen shot illustrating a sample Recruitment Simulator screen, within the Setup tab in Exhibit C. The fact that it shows Eligibility Criteria for a particular clinical trial protocol EST2190, further corroborates my recollection that the database that would drive the study site tool would include patient eligibility criteria for the protocol.

16. Exhibit E is a screen shot illustrating a sample Schedule screen, within the On Study tab in Exhibit C. The fact that it shows a series of tasks to be performed in a particular visit by a particular patient, including (among other tasks) instructions to perform a Chest X-Ray, evaluate Pulmonary Function, perform a Pelvic Exam, and

perform a Bone Scan, further corroborates my recollection that the database that would drive the study site tool would include post-enrollment instructions to have specified tests performed on a patient.

17. Exhibits F-H are screen shots generated by the SPONSOR.exe program when executed. Exhibit F illustrates the initial screen. It can be seen that the tool was to allow study sponsor physicians to view information regarding protocol authoring, among other things.

18. Exhibit G is a screen shot illustrating a sample Eligibility Checklist screen, within the Authoring tab in Exhibit F. The fact that it shows Eligibility Criteria for a particular clinical trial protocol EST2190, further corroborates my recollection that the database that would drive the study sponsor tool, as well, would include patient eligibility criteria for the protocol.

19. Exhibit H is a screen shot illustrating a sample Protocol Editor screen within the Authoring tab in Exhibit F. The graphic on this screen illustrates a study schema setting forth the visit sequences that a patient would follow according to the clinical trial protocol, and the tasks that would be performed on each visit, all as would be included in the ICP database. The fact that various tests would be performed on the patient at many of such visits corroborates my recollection that the database that would drive the study sponsor tool, as well, would include post-enrollment instructions to have specified tests performed on a patient.

**Diligence Toward Reduction To Practice**

20. FastTrack Systems worked diligently toward developing a working prototype of a system incorporating the invention. The development of the demo software was part of the process, and the same company that developed the demo software also worked on a Functional Specification which set out the detailed requirements that software programmers need to code the functional prototype.

21. Exhibit I, on information and belief, is a copy of pages 115-118 from Michael Kahn's second notebook. These pages appears to be his notes of a status meeting on October 20, 1999 with the development company, MONKEYmedia, which corroborates my recollection that MONKEYmedia were proceeding with their development of the Functional Specification.

22. Exhibit J, on information and belief, is a copy of page 140 from Michael Kahn's second notebook, which contains what appears to be his notes of an October 28, 1999 Board Meeting. The second "accomplishment" listed at the bottom of the page says, "Conducted market research, defined architecture and Release 1, started development." This note corroborates my recollection that development of the prototype was proceeding.

23. Exhibit K are the cover page and pages 12-17 and 22-23, from the version 1.0d05 of the Functional Specification. This document corroborates my recollection that development of the document by MONKEYmedia was still proceeding as of its date, which is December 17, 1999.

24. The description on pages 22-23 of Exhibit K, entitled "3 Eligibility Checklist", corroborates my recollection that the database in the prototype system would include patient eligibility criteria for the clinical trial protocol.

25. The description on pages 12-17 of Exhibit K, entitled "3 Patient Task Screens", concerns tasks that are to be performed on a particular patient on a particular visit. This particular description does not provide specific example tasks, but nevertheless it does corroborate my recollection that the database in the prototype system would include post-enrollment instructions to have specified tests performed on a patient.

26. Exhibit L, on information and belief, is a copy of page 63 from Michael Kahn's third notebook, which contains what appears to be his notes of a meeting on January 10, 2000. The list of attendees at this meeting includes Mr. Luke Brennan, who was a programmer hired to help code the prototype system. This document corroborates my recollection that by January 10, 2000 we had hired our first programmer to help code the prototype system.

27. FastTrack Systems also hired Mr. Rick Larsen, who started employment at FastTrack Systems in mid-February 2000 as Vice President of Engineering. One of Mr. Larsen's tasks was to oversee the further development of the prototype system.

28. Exhibit M is a spreadsheet which I understand was provided by Mr. Larsen, and which appears to be a schedule showing numerous tasks being performed and to be performed during the period March 13, 2000 and June 23, 2000, toward the development of the prototype. The document corroborates my recollection that the prototype system was in active development before, during and after the period March 13, 2000 through May 31, 2000.



Application No. 09/584,936

Atty Docket No. FSTK 1000-0

29. Accordingly, FastTrack Systems proceeded diligently, from a date prior to September 10, 1999, to a date later than May 31, 2000, toward an actual working prototype of the invention of the subject patent application.

30. All the activities described in this Declaration, as well as the preparation of each of the documents described in this Declaration, all took place in the United States.

31. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the application for any patent issued thereon or of any reexamination certificate.

DATED:

8/23/07  
MICHAEL MISCHKE-REEDS

**EXHIBIT A TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**EXECUTIVE SUMMARY**

# FASTTRACK Systems, Inc.

## Execuctive Summary

### What is FASTTRACK?

FASTTRACK is a clinical informatics and services company built around a network of domestic and international clinical trial sites and sponsors connected by advanced information technologies designed to greatly reduce the cost and improve the quality and timeliness of clinical trials. FASTTRACK focuses on Phase II and Phase III trials that are increasingly becoming the critical factor in time to market for new drugs.

### Why is FASTTRACK Important?

Over the next five years, pharmaceutical products worth \$30B in annual revenue will come off patent. In order to maintain the growth rates driving current valuations, the pharmaceutical industry must more than double the rate of new product introductions while maintaining current expense levels. Technologies such as combinatorial chemistry and high throughput screening have reduced the pre-clinical cycle time and the FDA Modernization Act and EU harmonization have reduced regulatory review times. But the human clinical trial time and costs have continued to grow. The time required for clinical trials now approaches 50% of the 14.7 years that it takes the average new drug to come to market. Time to market is often the most important factor driving pharmaceutical profitability -- a recent study demonstrated that the first drug-in-class to market averages a 50% market share with competing products dividing the remainder. In addition, the time for a second drug in a new class to appear in the market has decreased from six year to six month. An industry rule of thumb states that for a drug with billion-dollar market potential, each day spent in clinical trials reduces potential revenue by \$3 million due to patent expiration issues.

Clinical trials are expensive and trial costs are growing twice the rate of revenue growth. In US pharmaceutical companies alone, about \$8B or 40% of total pharmaceutical R&D is spent annually on human clinical trials. Spending on clinical trials is growing 15% per year, almost 50% above the industry's sales growth rate. Trials are growing both in number and complexity, growing from 30 trials per new drug application and less than 100 procedures per trial to almost 70 trials per application and about 160 procedures per trial, over the past 20 years. The trials process is largely paper-based and highly inefficient. In order to maintain growth and profitability, the pharmaceutical industry must significantly reduce the time and cost it takes to complete human clinical trials.

### What is FASTTRACK's Advantage?

FASTTRACK Systems is assembling a network of clinical trial sites that will be linked together using FASTTRACK's proprietary information technology. The FASTTRACK network provides a total integrated solution to the clinical trials process with significant advantages over fragmentary approaches, such as:

- An internet-based virtual network of "certified" and trained trial sites drawn from community clinics, specialty networks and academic centers, all which will use FASTTRACK technology to deliver efficient accrual, accurate and timely data collection and reporting, and real-time trial monitoring and compliance.
- A direct e-commerce connection between sponsors and sites that will help both parties to meet their trial goals.
- Advanced medical informatics technology that automatically generates all workflow procedures, data collection, and documentation based on the trial protocol, assuring strict adherence to protocol specifications, responsiveness to protocol changes, and timely collection of data at the point of care.
- Central resources of software and databases that can assist both sponsor and site in optimizing trials and trial accrual, including accrual modeling, cost analysis, and trial enrollment.

The heart of FASTTRACK's technology is the Intelligent Clinical Protocol (ICP). The clinical protocol is the foundation of every trial and largely determines the time, cost and ultimate success or failure of the trial. All parts of a trial, including recruitment, treatment, data requirements, trial management and reporting, flow from detailed specifications contained in the protocol. FASTTRACK believes that a system driven by the fundamental protocol provides the best solution for improving the trial process.

The ICP begins with a protocol authoring tool that exploits detailed knowledge bases such as trial design templates, historical and competing clinical trials, actual medical procedure costs, anonymized patient clinical summaries, FDA and European regulatory requirements, pre-clinical pharmacokinetic and pharmacodynamic models and statistical parameters to assist the pharmaceutical medical director optimize study design and model all aspects of the clinical development process. FASTTRACK software automatically translates the protocol into an intelligent electronic Case Report Form (eCRF) to be transmitted electronically to the physicians performing trials. Anticipating the rapid growth of electronic medical records, the eCRF will automatically screen the physician's or institution's current patient records to determine trial eligibility.

Following enrollment, FASTTRACK protocol-directed workflow management software will generate appropriate role-specific task lists to ensure that the physician, nurses and other staff execute the trial tasks as specified in the protocol. Finally, FASTTRACK standard point of care data collection devices to ensure that all required data is captured in real time and is automatically 'reality & quality checked' while the patient is in the physician's exam room.

Results will be uploaded to FASTTRACK's repository, checked by on-line queries, and loaded into the sponsor's database for statistical analysis and subsequent FDA/EMEA submission. Using highly sophisticated temporal trending and abstraction technology, the FASTTRACK database can continuously search for complex evolving patterns such as subtle but progressive toxicity or adverse events. Following approval, FASTTRACK expects to repackage this information for the sponsor's marketing group to accelerate sales ramp-up. FASTTRACK network sites will also continue data collection after the trial is over for additional marketing and post-marketing surveillance purposes.

Additional direct benefits to the study sponsors include: rapid analysis of interim study results, immediate implementation of any mid-study protocol modifications, near real-time monitoring of patient accrual and other project milestones, and point-of-service data validation and quality assurance. Direct benefits to study locations include: rapid patient accrual using automated screening tools, automatic protocol modifications without manual intervention, automated workflow and task lists for improved study productivity and throughput, and electronic data capture eliminating paper piles. The use of automated processes will eliminate many oversight steps which currently are done manually. Removing the manual tasks will significantly reduce direct labor costs, travel expenses, and time-to-database-lockdown.

FASTTRACK will deliver its information services to sponsors, CROs and sites over the Internet using a central application service provider (ASP) and thin-client model that supports multiple user devices including workstations and hand-held computers. This approach will reduce cost, complexity and learning times for its users, providing them with service-based solutions rather than simply software. It also provides a direct connection between trial sites and sponsors, eliminating much of the inefficiency associated with middlemen services. All software and data will be centrally maintained for reasons of efficiency and security. Confidentiality will be maintained through strict use of modern encryption protocols and standards.

#### *What is FASTTRACK's Business Model?*

FASTTRACK will provide its solutions using a service-based business model in which FASTTRACK rather than sponsors or individual sites take responsibility for the entire trial process. This will eliminate the need for sponsors or sites to learn and support the complex technology underlying FASTTRACK and permit them to focus on the trials themselves. It will also eliminate the need for large up-front investments in equipment, software and training.

The FASTTRACK network will incorporate clinical specialty networks, community practices and academic medical centers. Each site will use the FASTTRACK information system to recruit patients, manage their trials and deliver information to sponsors. FASTTRACK will maintain a central data base that will improve accrual efficiency and provide sponsors with quantitative proof of FASTTRACK network sites' ability to deliver patients and produce high-quality data in a timely and cost-efficient manner. FASTTRACK will also provide a central clearinghouse function so that sites can learn about other trials for which their particular patient

populations would be appropriate, thereby increasing the number of trials in which they can participate. FASTTRACK's customers will include pharmaceutical organizations, CROs, SMOs and its network of trial sites. Its revenues will be derived from:

- Licenses for the protocol authoring tool based on number of trials for which it is used by each sponsor.
- Sponsor access to the central FASTTRACK anonymized database for recruitment simulation and protocol refinement and other knowledge bases, such as cost databases and population-based accrual estimates.
- Trial management and reporting services for each site using a combination of transaction and subscription pricing models.
- Sales of anonymized data to support sponsor marketing programs.
- Specialized services to support electronic data submission and other regulatory reporting requirements.
- Queries of practice locations regarding interest in potential studies or estimates of availability of unusual patient populations, marketing dynamics, longitudinal outcomes studies.
- Addition of specialized non-protocol-required screening variables, such as functional status measures, which can be used as alternative endpoints should a clinical study fail to meet its designed endpoints.
- Addition of specialized non-protocol-required variables, such as insurance status, which can be used by the site practice management administration for detailed clinical-financial evaluation of local case-mix and practice patterns.

FASTTRACK intends to focus initially on trials involving drugs with complex protocols, high patient surveillance requirements, high activity intensity, high data volume and large market potential. Examples include oncology, HIV, cardiovascular and neuroactive drug trials. Once the FASTTRACK service is operating smoothly and its fixed costs are covered the Company will expand the service to other drugs and possibly devices.

### Who is FASTTRACK?

FASTTRACK has assembled an executive management team of world-renowned leaders in medical informatics, clinical drug development and commercial clinical software development and proven start-up and high growth management experience. Members of the FASTTRACK Clinical Advisory Board and the Scientific Advisory Board represent world class, success-driven leaders in their fields from institutions such as Stanford University, Washington University in St. Louis, and the National Cancer Institute. The team has played central roles in the development of such drugs as zidovudine (Retrovir™), paclitaxel (Taxol™), doxorubicin (Doxil), mitoxantrone (Novantrone™), cis-platinum (Platinol™), didanosine (Videx™), zalcitabine (Hivid™). FASTTRACK Systems is funded by CW Ventures and ARCH Ventures, two of the leading healthcare venture capital funds that have been responsible for founding

such leading edge companies as Athena Neurosciences, Aurora Biosciences, Caliper Technologies, Millenium Pharmaceuticals, Pharmacopeia, Sugen Pharmaceuticals and Vertex Pharmaceuticals.

**Summary – The FASTTRACK Advantage**

FASTTRACK provides the solution by which pharmaceutical companies will overcome the key bottleneck in getting new drugs to market. By offering a total set of information solutions and services for trials development and management based on unique technology it expects to revolutionize the way trials are conducted, taking significant costs and time out of the system and improving the overall success rate of the process. It provides direct, synergistic benefits to both sites and sponsors, creating a “win-win” for all participants in the clinical trial arena. We invite your inquiries about how we can help you.

**EXHIBIT B TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF DIRECTORY LISTING**



D:\FastTrack Systems\Demos\Version 2.1.1

File Edit View Favorites Tools Help



Back



Search



Folders



Address D:\FastTrack Systems\Demos\Version 2.1.1

Name	Size	Type	Date Modified	Location
<b>F</b>				
FastTrack_SP_v2.1.1.zip	1,349 KB	WinZip File	8/15/1999 10:39 PM	Files Currently on the
FastTrack_ST_v2.1.1.zip	1,365 KB	WinZip File	8/15/1999 10:32 PM	Files Currently on the
FastTrack-SITE.dir	4,497 KB	DIR File	8/5/1999 12:20 PM	Files Currently on the
FastTrack-SPONSOR.dir	4,195 KB	DIR File	8/5/1999 12:19 PM	Files Currently on the
<b>S</b>				
SITE.exe	1,619 KB	Application	7/20/1999 6:49 AM	Files Currently on the
SPONSOR.exe	1,619 KB	Application	7/20/1999 6:51 AM	Files Currently on the

**EXHIBIT C TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF SITE.EXE,  
INITIAL SCREEN**

SETUP

ACCRUAL

ON-STUDY

USER:  
Smith, Pat

ROLE:  
Physician

LOGOUT



Patients



Protocols



Sites



FT Net



Reports

CONFIDENTIAL  
Copyright 1999 FastTrack Systems

**EXHIBIT D TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF SITE.EXE,  
SAMPLE RECRUITMENT SIMULATOR SCREEN**

## Recruitment Simulator

Location: All Sites  
Disease: Breast Cancer  
Protocol: EST2190

Run Search

Breast cancer patients:

Eligibility Criteria	Matching Patients	
	Single	Combined
Gender = Female		
Age between 15 and 60		
Previous Treatment: mastectomy or lumpectomy		
Hormone receptor status = positive		
# involved lymph nodes >= 10		
Primary tumor status is not T4		
Lymph node status is not N2		
Metastatic disease is not present		

Total Matching Patients:

Export to Excel

USER:  
Smith, Pat

ROLE:  
Physician

LOGOUT

SETUP

Patients

Protocols

Sites

FT Net

Reports

ACCRUAL

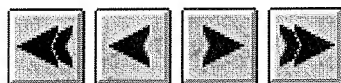
ON-STUDY

**EXHIBIT E TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF SITE.EXE,  
SAMPLE SCHEDULE SCREEN**

# Schedule

Day Week Month



Role: Show All

June 4, 1999

Visit: Post-Chemo. Phase (Week 36)

09:00	Joe M.
09:15	Sue C.
09:30	Liz B.
09:45	Doug H.
10:00	Pat J.
10:15	John P.
10:30	
10:45	Ellie Y.
11:00	Chris K.
11:15	Ann R.
11:30	Mike W.
11:45	
12:00	
12:15	
12:30	
12:45	
13:00	Mark G.
13:15	Jane I.

<input type="checkbox"/>	History & Physical Exam	Physician
<input type="checkbox"/>	ECOG Performance Status	Nurse
<input type="checkbox"/>	Draw blood samples	Phlebotomist
<input type="checkbox"/>	Enter laboratory results	Coordinator
<input type="checkbox"/>	Chest X-Ray	Outside referral
<input type="checkbox"/>	Pulmonary Function	Outside referral
<input type="checkbox"/>	Pelvic Exam	Physician
<input type="checkbox"/>	Bone Scan	Outside referral
<input type="checkbox"/>	Chemo. Questionnaire	Nurse

New

Edit

Remove

USER:  
Smith, Pat

ROLE:  
Physician

LOGOUT

Patients

Protocols

Sites

FT Net

Reports

ON-STUDY

SETUP

ACCRUAL

30

**EXHIBIT F TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF SPONSOR.EXE,  
INITIAL SCREEN**



PLANNING

AUTHORING

DOCUMENT MGR

USER:  
Smith, Pat  
ROLE:  
Physician

LOGOUT



Diseases



Trials



Sites



FT Net



Reports

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**EXHIBIT G TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF SPONSOR.EXE,  
SAMPLE ELIGIBILITY CHECKLIST SCREEN**

## Eligibility Checklist

### EST2190: Inclusion Criteria

[Add](#)[Edit](#)[Remove](#)

Epithelial breast cancer  
Age between 15 and 60  
# involved lymph nodes  $\geq 10$   
Gender = Female  
Previous treatment: mastectomy or lumpectomy  
Hormone receptor status = Positive  
ECOG performance status = 0 or 1  
WBC  $\geq 4,000$   
Platelets  $\geq 100,000$   
Alkaline Phosphatase  $\leq 1.2$  times normal

### EST2190: Exclusion Criteria

[Add](#)[Edit](#)[Remove](#)

Primary tumor status not = T4  
Previous treatment not = chemotherapy  
Previous treatment not = radiation therapy  
Lymph node status not = N2  
Metastatic disease is not present  
Not pregnant or lactating  
No history of heart disease  
No symptomatic CNS disease

[Reset](#)[Cancel](#)[Save](#)

PLANNING

ORDER

ORDER

00

00

DOCUMENT MGR

USER:  
Smith, Pat

ROLE:  
Physician

[LOGOUT](#)

AUTHORING

Diseases

Trials

Sites

FT Net

Reports

**EXHIBIT H TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**SCREEN SHOT OF SPONSOR.EXE,  
SAMPLE PROTOCOL EDITOR SCREEN**

## Protocol Editor

Trial Name: EST2190

Version: January 12, 1997

Title: A Phase II Study of Conventional Adjuvant Chemotherapy versus High Dose Chemotherapy

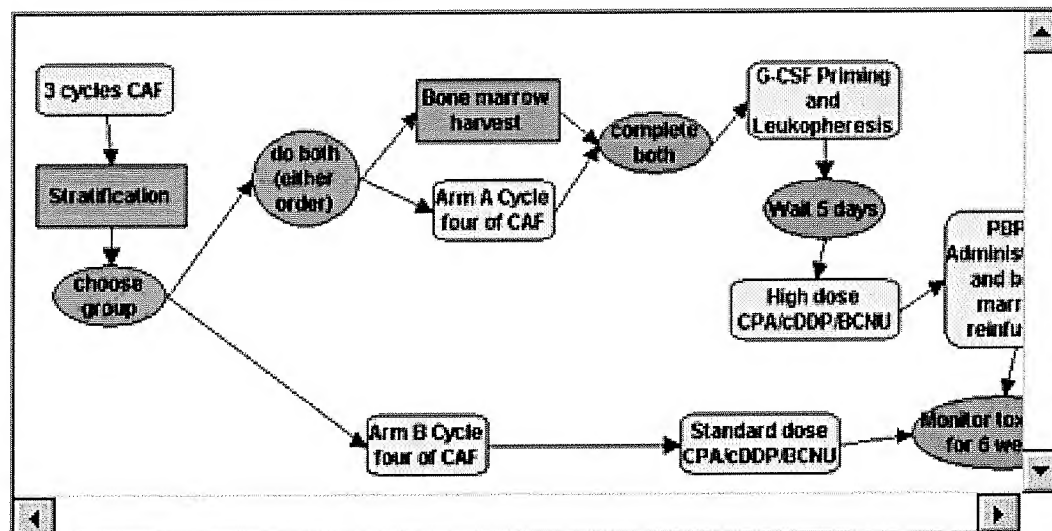
Authors: Doe, John  
White, Chris  
Smith, Pat

Step: Action\_Step

Add

Edit

Remove



Eligibility

Recruitment

Budget

Regulatory

Library

USER:  
Smith, PatROLE:  
Physician

LOGOUT

Diseases

Trials

Sites

FT Net

Reports

**EXHIBIT I TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**PAGES 115-118 FROM SECOND NOTEBOOK OF  
MICHAEL KAHN**

20 Oct 99

## Requirements Group

Monkey Media - prototyping / GUI

Concept 5 - infrastructure

- ① WF Models
- ② MM Storyboards
- ③ Req List

Brent's document:

mc/BB documents - fine grained documentation

Status: mc/BB

Accrual modeling (~40% done)

List of use cases P&amp;X (10 cases) ~40% done

Concurrent issues list

Requirements document more integrated

Study setup list

Task Management

Data Capture - Rev 2

Overall Features

Project Management / Dashboard (may after setup/accrual)

Product Feature List: In/Out

Accrual "issues"

Site Setup: Installation

Training

Interfaces

Investigator CUs

IRB

- |   |  |                              |
|---|--|------------------------------|
| ① | Pre-screening                                    | Quick Screen <1 min          |
| ② | Eligibility Review using standard of care values | Eligibility Checklist <2 min |
| ③ | Consent  |                              |
| ④ | Study-specific screening protocol / values       | Eligibility Checklist CRF    |
| ⑤ | Enroll   |                              |
| ⑥ | Treatment protocol                               | Task List by Visit           |

### Type of Treatment (treatment modalities)

Screening Patients based on QS features

Screening Studies based on patient/provider preferences

#### Task Management

- Consent process
- Screening tools
- Enrollment

PDQ groups by stage of disease + some special category  
Stage 1 or Stage 2 Rx -

: Most are Chemor

or Chemo + Immunotherapy

- couple of trials = surgery difference
- couple of trials = different RT
- nutrition/exercise
- quality of life



## Dashboard

### ① Multitrial Summary

	Status	Metrics
Trial 1		
Trial 2		
Trial 3		

### ② Sequential Summary

	Status	Issues	Ver / Steps
Patient 1			
Patient 2			
Patient 3			

### ③ Patient View

	Expected Visit Date	Actual Visit Date	tasks completed	issues
visit 1				
visit 2				
misc notes				

### ④ Calendar View (by role??)

Tuesday	Wednesday	Thursday
-	-	-
-	-	-
-	-	-
-	-	-

### To Do / Reminder / Alert

- ① Trial Setup "In Box"
- ② Queries or Issues outstanding
- ③ Patient Visits Oriental Visit
- ④ AE follow-up
- ⑤ Missed visit

### Site Setup → Patient (CUs)

### Study Setup

- Evaluate proposal (Budget, Recruitment)
- Staging (IRB, consent)

~~From~~ -

Milestones

Inventory

NP/AR

Capacity; Resource Planning

**EXHIBIT J TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**PAGE 140 FROM SECOND NOTEBOOK OF MICHAEL  
KAHN**

28 Oct 99 Board Meeting

Bob Nelson  
Antone

Approved: Minutes 9/13/99

10,000 shares Kohone

Declarative

\$750,000 budget \$750,000

6% / annum

Due & payable in 30 days demand  
demand no earlier than 6/1/2000.

If Preferred B  $\geq$  \$5M, with at least 1 new option investor,  
the outstanding principal & interest will be  
converted into Preferred B shares.

If Preferred B  $<$  \$5M, the holder will have the  
option to convert outstanding principal & interest into  
Preferred B shares.

Warrant: 10% of the loan amount

Warrant exercise price = Preferred B price

Warrant Term = 3 years.

Accomplishments:

Recruited team, setup office

Conducted market research, defined architecture and Release 1, started development

Recruited sites & sponsors, started WF analysis

Initiated partner discussions

Developed financial model, business plan & presentation

Initiated investor discussions

**EXHIBIT K TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**FUNCTIONAL SPECIFICATION V1.0D05,  
COVER PAGE AND PAGES 12-17 AND 22-23**



*Information architecture  
Interaction technique  
Interface design*

**FastTrack Systems**

# **Functional Specification**

**by MONKEYmedia**

version 1.0d05  
December 17, 1999

**CONFIDENTIAL**

## 2. Patient List

**Patient List**

Today's visit (January 1, 2000)

09:00 - Edwards, Jill (IN)
09:15 - Doh, Jane (HS)
09:30 - Boe, Pam (IN)
09:45 - Young, Christine (IN)
10:00 - Smith, Betty (C1)
Green, Joan (C1)
Stephens, Mae (C1)
10:15 - Rogers, Sandy (PC)
10:30 - Moe, Pat (C2)
10:45 - Opus, Lisa (C1)
11:00 - Kay, Sue (IN)
11:15 - Ingram, Liz (C1)
Ann, Deb (C1)
11:30 - White, Susie (HS)
11:45 - Groene, Jill (HS)

Note:  
IN = initial screening visit  
HS = history  
C1 = chemo cycle I  
C2 = chemo cycle II  
PC = port-chemo followup

Logout

**Figure 7 - Task List: Patient List**

A successful login from the Patient List Log-in [1] leads to the Patient List. This screen allows access to all the patients scheduled at the clinic for that particular day

A user with patient list access rights selects the patient whose tasks will be displayed on the task list screens [3] by clicking on the appropriate patient.

The patient list is also the parking spot for the unit before it is put into the pre-docking state.

After a predetermined interval of time without user input, the system times out, logs the current user out and blanks the screen per Sleep Screen#1 [1.1].

## 3. Patient Task Screens

This area of functionality includes several different sub-sections:

- 3.1 — the Full Task List
- 3.2 — the Outstanding Tasks List
- 3.3 — the Task Info Screens

A user will arrive at this series of screens in one of two ways:



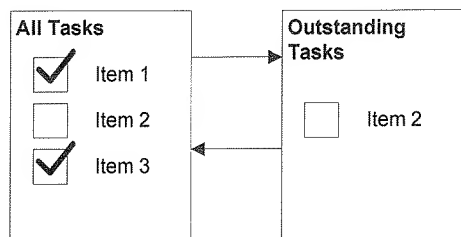
- As a staff member with "change patient" rights who has selected a different patient's tasks to view from the patient list [2].
- As a role player who is currently completing one of the listed tasks. This role will login via Login Screen #2 [4].

After a predetermined interval of time without user input, the system times out, saves any data that has been entered, logs the current user out, and blanks the display per 4.

#### **Assumptions**

The tasks listed are determined by two prerequisites:

- Clinical coordinator has reviewed all tasks associated with a particular patient visit and validated the tasks.
- Protocol-mandated tasks have been entered into the FTS by the FTS staff, such that the task list reflects the protocol.



**Figure 8 - Task List: All Tasks v. Outstanding Tasks**





### 3.1 Patient Identifier Screen

**Confirm Correct Pt.**

Patient Name:	<b>Jane Doe</b>
Visit Date:	<b>January 1, 2000</b>
Disease Area:	<b>Oncology</b>
Trial Name:	<b>Nu-DrugXYZ123</b>
Visit#:	<b>6 (from 10)</b>
Med Rec#:	<b>555-12-3456</b>

Done w/ Role

Done w/ Pt.

**Figure 9 - Task List: Patient Identifier Screen**

The user will use the following patient identifiers to confirm that the patient at hand matches the patient whose data is on the handheld unit.

- Patient name
- Visit date
- Disease area
- Trial name
- Visit number
- Medical record number
- Current user

This may be an independent screen or it may be embedded in the Full or Outstanding Task List.

If this is an independent screen, a predetermined interval of time without user input causes the system to time out, log of the current user, and blank the screen per [4].

If this is a separate screen, re-login from sleep/login screen #2 [4] could lead to this screen before the task list to help users avoid errors in patient care.



### 3.2 Full Task List

All Tasks

See Outstanding Items Only

1 ☒ Item 1

2 ☒ Item 2

3 ☐ Item 3

4 ☒ Item 4

Others/Notes

Reset

Done w/ Role

Done w/ Pt.

**Figure 10 - Task List: Full Task List**

The Full Task List includes all of the tasks associated with a particular patient visit for a particular day. This screen is the default view upon role-based login. A comment field at the bottom of the screen displays any notes the clinical coordinator has written to the staff members who will see the patient. Alternately, a staff member may enter a note for the clinical coordinator.

Information on any task may be obtained by clicking on the "info" button next to the item. This will open the Task Info Screen [3.3].

The [Reset] button returns the data to the state it was in before the most recent login.

After a task has been completed, the user checks it off in the list. When all the tasks associated with a role have been completed, the user clicks the [Done with Role] button. This action saves the data that has been entered and leads to Sleep/Login Screen #2 [4].

If some of the tasks associated with a role have not been completed before the user clicks [Done with Role], they will migrate from the Full list to the Outstanding list [3.2]. The user may toggle between the Full List and the Outstanding List using the appropriate button.

When all the tasks associated with a patient have been completed — and before the patient exits — the clinical coordinator reviews the task list. Any missing data may be gathered at that time, staff, supply, and patient availability permitting.

If no data is missing or it is not feasible to address any discrepancies at the time, the clinical coordinator may click the [Done with Patient] button to close the task list. This action saves all the data that has been entered and produces the Patient Rights Login Screen [5].



After a predetermined interval of time without user input, the system times out, saves any data that has been entered, logs the current user out, and blanks the display per 4.

There are pros and con's to using the reset button.

- Pro: It allows clearing of inadvertent entries
- Con: It risks creating confusion and clutter in the limited real estate.

### 3.3 Outstanding Tasks List

Outstanding Tasks

See Full Task List

3 ☐ Item 3

Others/Notes

Reset

Done w/ Role

Done w/ Pt.

**Figure 11 - Task List: Outstanding Tasks**

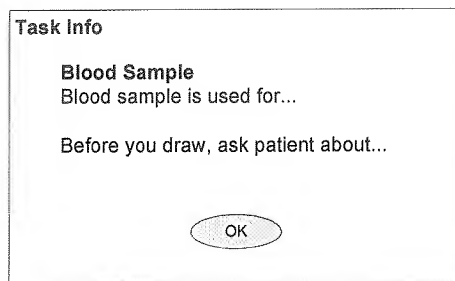
The Outstanding Tasks List displays any items that remain to be addressed before the end of a patient visit. As noted above, all tasks not checked off by a role populate this screen.

Information on any task may be obtained by clicking on the "info" button next to the item. This will open the Task Info Screen [3.3].

After a predetermined interval of time without user input, the system times out, saves any data that has been entered, logs the current user out, and blanks the screen as per 4.

### 3.4 Task Info Screen





**Figure 12 - Task List: Task Info Screen**

Information about tasks is displayed on this screen. Clicking [OK] will take the user back to either the Full Task [3.1] or the Outstanding Tasks List [3.2].

After a predetermined interval of time without user input, the system times out, saves any data that has been entered, logs the current user out, and blanks the screen as per 4.

When the user checks off an item in the Outstanding List, then selects info on a task, the data may either remain on that screen or migrate to the Full List.

#### **4 .Sleep/ Login Screen #2**

Visually, this screen resembles Login Screen #1. For a full discussion of the functionality of the Login screens, see Chapter 5, "Ubiquitous Controls and Affordances."

This screen serves as the portal for a return to the Task List [3].

Sleep Screen #2 is a result of timeouts from the Task List [3], Login #2 [4], Failure Message #2 [4.1], Patient Rights Login [5] and Failure Message #3 [5.1].

#### **5. Patient Rights Login Screen**

Visually, this screen resembles the Patient Rights Login of Section One.

This screen inherits all the properties and rules of general Login and Sleep functionality as described in Chapter 5, "Ubiquitous Controls and Affordances," with the exception of the addition of a [Cancel] button to allow a return to the Task List [3].

A successful login takes the user to the patient list, while timeout from this screen takes the user to a login screen that leads back to the task list.



user to the Eligibility Checklist [3] for the trial. Clicking on [Back to QuickScreen] takes the user to the QuickScreen screen [1].

## 2.1 Trial Info #1

**Trial Info**

**Trial: NUDRUG-XYZ123**

The success of adjuvant therapy stems from its potential ability to eradicate pre-clinical microscopic metastases. The bone marrow is a frequent site of breast cancer metastases.

Back to List of Trials      Check Eligibility for This Trial

Figure 16 - QuickScreen: Trial Info #1

This screen will display a brief description of the trial selected by the user. The description may include a brief outline of some of the steps in the trial as well as details about what data the sponsor is looking for or what symptoms the drug addresses.

From this screen, the user may return to the Browse Trial Results screen [2] by clicking [Back to List of Trials] or go on to check eligibility by clicking on [Check Eligibility for This Trial].

## 3 Eligibility Checklist

**Eligibility Checklist**

**Trial: NUDRUG-XYZ123**

**Inclusion Criteria:**

1. Epithelial breast cancer
2. Age between 15 and 60
3. # involved lymph nodes  $\geq 10$
4. Gender = Female
5. Previous treatment: mastectomy or lumpectomy
6. Hormone receptor status = Positive
7. ECOG performance status = or 1
8. WBC  $\geq 4,000$
9. Platelets  $\geq 100,000$
10. Alkaline Phosphatase  $\leq 1.2$  times normal
11. Bilirubin  $\leq 1.2$  times normal
12. SGOT  $\leq 1.2$  times normal
13. Ejection fraction (MUGA)  $\geq 50\%$

**Exclusion Criteria:**

1. Primary tumor status not = T4

Back (Select a Different Trial)      Back to QuickScreen      Qualify

Figure 17 - QuickScreen: Eligibility Checklist



This screen is used to determine if the patient qualifies for a particular trial by viewing certain inclusion and exclusion criteria. These criteria will be trial specific.

As on the trial listing screen, more information about the trial can be read by clicking on the trial name below the patient identifiers. This leads to Trial Info #2 [3.1].

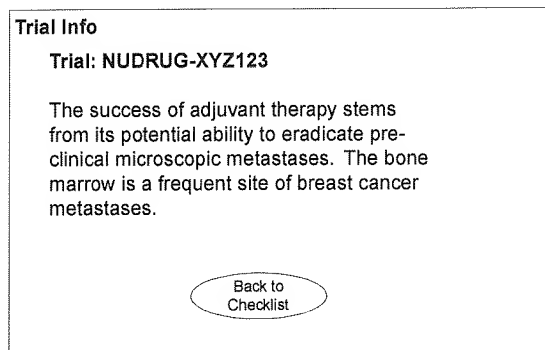
The user also has the option of returning to the Browse Trial Results [2] screen to select a different trial by clicking the [Back] button. A return to the QuickScreen may be accomplished by clicking [Back to QuickScreen].

Clicking [Qualify] produces the Qualification Confirmation Screen [4]. This button does *not* cause the unit to perform any calculation of eligibility.

Open issues related to this screen include:

- The number of trials, with all their different criteria, that the handheld unit can store.

### 3.1 Trial Info #2



**Trial Info**

**Trial: NUDRUG-XYZ123**

The success of adjuvant therapy stems from its potential ability to eradicate pre-clinical microscopic metastases. The bone marrow is a frequent site of breast cancer metastases.

Back to Checklist

**Figure 18 - QuickScreen: Trial Info #2**

This screen will display a brief description of the trial selected by the user. The description may include a brief outline of some of the steps in the trial as well as details about what data the sponsor is looking for or what symptoms the drug addresses.

From this screen, the user may **ONLY** return to the Eligibility Checklist screen [3].

**EXHIBIT L TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**PAGE 63 FROM THIRD NOTEBOOK OF MICHAEL KAHN**

10 Jan 00

63

MMR

CBC

Luke Brennan

Ernst Trepper

Paul Nadler

Site Boston Line  
Sponsor Boston Line  
Developer Boston Line

Context:

- ① 1.0, 1.5, 2.0 - what they mean
- ② Review state of requirements summary document
- ③ Work thru list

Release 1.5 = "bear the weight"

1.0 = "initial stepping stone" - mostly site assumptions

2.0 = "different beast"

Sponsor

Accrual simulation

Site selection

Investing site behavior

- via payments

Tracking metrics



**EXHIBIT M TO DECLARATION OF INVENTOR  
MICHAEL MISCHKE-REEDS  
UNDER 37 C.F.R. §1.131(b)**

**PROTOTYPE DEVELOPMENT SPREADSHEET,  
MARCH 13, 2000 - JUNE 23, 2000**

ID	Task_Name	Duration	Start_Date	Finish_Date	Predecessors	Resource_Names
1	release 1.0a prime	70 d	3/13/2000 8:00	6/23/2000 17:00		
2	this is a modified 1.0a plan that also includes simple trial/visit QS	1 d	3/13/2000 8:00	3/13/2000 17:00		
3		1 d	3/13/2000 8:00	3/13/2000 17:00		
4	Dependencies	49 d	3/20/2000 17:00	5/26/2000 17:00		
5	finalize requirements/use cases	0 d	3/20/2000 17:00	3/20/2000 17:00		arian
6	AvantGo	1 d	4/14/2000 8:00	4/14/2000 17:00		AvantGo
7						
8	informatics	43 d	3/29/2000 8:00	5/26/2000 17:00		
9	Quickscreen and visit task	43 d	3/29/2000 8:00	5/26/2000 17:00		
10	define model tags and structure	1 d	3/29/2000 8:00	3/29/2000 17:00		mike kahn
11	protocol data(for unit testing)	1 d	5/3/2000 8:00	5/3/2000 17:00		mike kahn
12	final protocol data	1 d	5/26/2000 8:00	5/26/2000 17:00		mike kahn
13	final for beta	1 d	5/12/2000 8:00	5/12/2000 17:00		mike kahn
14						
15	development	53.75 d	3/13/2000 8:00	5/25/2000 15:00		
16	infrastructure	40.75 d	3/13/2000 8:00	5/8/2000 15:00		
17	abstract entity bean framework	25.18 d	3/13/2000 8:00	4/17/2000 9:28		
18	design	1.25 d	3/13/2000 8:00	3/14/2000 10:00		allen[80%]
19	review/updates	1.25 d	3/14/2000 10:00	3/15/2000 12:00	18	phil[80%]
20	training	2.5 d	3/15/2000 13:00	3/17/2000 17:00	19	allen[80%]
21	code/unit test	7.5 d	4/5/2000 14:28	4/17/2000 9:28	61	phil[80%]
22						
23	jsp framework	5 d	3/13/2000 8:00	3/17/2000 17:00		
24	design	1.25 d	3/13/2000 8:00	3/14/2000 10:00		matt[80%]
25	review/updates	1.25 d	3/14/2000 10:00	3/15/2000 12:00	24	matt[80%]
26	code/unit test	2.5 d	3/15/2000 13:00	3/17/2000 17:00	25	matt[80%]
27						
28	security	38.25 d	3/15/2000 13:00	5/8/2000 15:00		
29	jsp	38.25 d	3/15/2000 13:00	5/8/2000 15:00		
30	modeling	8 d	3/15/2000 13:00	3/27/2000 12:00	25	john[50%]
31	Modeling/Review Security Expertise	1 d	3/27/2000 13:00	3/28/2000 12:00	30	Security Architect
32	review/update	8 d	3/28/2000 13:00	4/7/2000 12:00	31	john[50%]
33	code/unit test	6.25 d	4/28/2000 13:00	5/8/2000 15:00	32,133	matt[80%]
34	data level	35.18 d	3/15/2000 13:00	5/3/2000 14:28		
35	modeling	8 d	3/15/2000 13:00	3/27/2000 12:00	19	john[50%]
36	Modeling/Review Security Expertise	1 d	3/27/2000 13:00	3/28/2000 12:00	35	Security Architect
37	review/update	8 d	3/28/2000 13:00	4/7/2000 12:00	36	john[50%]
38	code/unit test	6.25 d	4/25/2000 11:28	5/3/2000 14:28	37,136	sidharth[80%]
39	Business Processes	52.68 d	3/13/2000 8:00	5/24/2000 14:28		
40	use case work	7 d	3/21/2000 8:00	3/29/2000 17:00		
41	use case kick-off	1 d	3/21/2000 8:00	3/21/2000 17:00	5	phil,peter,kelly,mike
42	quickscreen use case	2 d	3/22/2000 8:00	3/23/2000 17:00	41	mike[80%]
43	quickscreen synch	2 d	3/22/2000 8:00	3/23/2000 17:00	41,26	matt[80%]
44	handheld login	2 d	3/22/2000 8:00	3/23/2000 17:00	41	phil[80%]
45	resynch	2 d	3/22/2000 8:00	3/23/2000 17:00	41	peter[80%]
46	protocol loader	2 d	3/22/2000 8:00	3/23/2000 17:00	41	kelly[80%]
47						
48	Task Visit Browse/View	4 d	3/24/2000 8:00	3/29/2000 17:00	41,42	mike[40%]
49						
50	use case reviews	6.25 d	3/24/2000 8:00	4/3/2000 10:00		
51	review with domain experts	2 d	3/24/2000 8:00	3/27/2000 17:00	42,43,44,45,46	phil[80%],mike[40%],matt[80%]
52	review with developers	0.68 d	3/28/2000 8:00	3/28/2000 14:28	51	phil[80%],mike[40%],matt[80%]
53						
54	review Task Visit Browse/View	1.25 d	3/30/2000 8:00	4/3/2000 10:00	48	mike[40%]
55						
56	Business Concept Model	6 d	3/28/2000 14:28	4/5/2000 14:28		
57	business concept model	5 d	3/28/2000 14:28	4/4/2000 14:28	52	phil[80%]
58	business concept model	2 d	3/28/2000 14:28	3/30/2000 14:28	52	mike[40%]
59	business concept model	1 d	4/3/2000 10:00	4/4/2000 10:00	54,58	mike[80%]
60	business concept model	5 d	3/28/2000 14:28	4/4/2000 14:28	52	peter[80%]
61	business concept model review	1 d	4/4/2000 14:28	4/5/2000 14:28	60,57,59	peter,phil,mike,kelly
62						
63	entity beans	18.75 d	4/5/2000 14:28	5/2/2000 11:28		
64	modeling	3.75 d	4/5/2000 14:28	4/11/2000 11:28	61	sidharth[80%]
65	review	1.25 d	4/11/2000 11:28	4/12/2000 14:28	64	sidharth[80%]
66	code/unit test	12.5 d	4/12/2000 14:28	5/1/2000 9:28	65,114	rick[80%]
67	code/unit test	5 d	4/24/2000 9:28	5/1/2000 9:28	65,125	phil[80%]
68	code review	1.25 d	5/1/2000 9:28	5/2/2000 11:28	66	rick[80%]
69						
70	ddl	3.75 d	4/14/2000 16:28	4/20/2000 14:28		
71	update	1.25 d	4/14/2000 16:28	4/18/2000 9:28	65,141	kelly[80%]

72	review	1.25 d	4/18/2000 9:28	4/19/2000 11:28	71	kelly[80%]
73	run	1.25 d	4/19/2000 11:28	4/20/2000 14:28	72	kelly[80%]
74						
75	Quickscreen	34.93 d	4/3/2000 10:00	5/22/2000 9:28		
76	design ui navigation	2.5 d	4/3/2000 10:00	4/5/2000 15:00	50,43	matt[80%]
77	ui (JSP)	4.13 d	4/5/2000 15:00	4/11/2000 16:00		
78	design	1 d	4/5/2000 15:00	4/6/2000 15:00	76,61	peter[80%],mike[80%]
79	review	0.63 d	4/6/2000 15:00	4/7/2000 11:00	78	peter[80%],mike[80%]
80	qa review	0.5 d	4/6/2000 15:00	4/7/2000 10:00	78	qa
81	code/unit test	2.5 d	4/7/2000 11:00	4/11/2000 16:00	80,79	peter[80%]
82	session beans	27.5 d	4/12/2000 14:28	5/22/2000 9:28		
83	design	1.25 d	4/12/2000 14:28	4/13/2000 16:28	76,65	sidharth[80%]
84	review	1.25 d	4/13/2000 16:28	4/17/2000 9:28	83	sidharth[80%]
85	code/unit test	3.75 d	5/2/2000 11:28	5/22/2000 9:28	84,68	rick[80%]
86	code unit test	1.25 d	4/17/2000 9:28	4/18/2000 11:28	84,81	peter[80%]
87						
88	Quickscreen synchronization	52.68 d	3/13/2000 8:00	5/24/2000 14:28		
89	design ui navigation	2.5 d	4/5/2000 15:00	4/10/2000 10:00	76,50	matt[80%]
90	investigation	6.25 d	3/13/2000 8:00	3/21/2000 10:00		
91	download new AvantGo	2.5 d	3/13/2000 8:00	3/15/2000 12:00		cris[80%]
92	testing	3.75 d	3/15/2000 13:00	3/21/2000 10:00	91	cris[80%]
93	ui (JSP)	6.56 d	4/10/2000 10:00	4/18/2000 15:30		
94	design	1.56 d	4/10/2000 10:00	4/11/2000 15:30	89	allen[80%]
95	review	1.25 d	4/11/2000 15:30	4/13/2000 8:30	94	allen[80%]
96	qa review	1 d	4/11/2000 15:30	4/12/2000 15:30	94	qa
97	code/unit test	3.75 d	4/13/2000 8:30	4/18/2000 15:30	96,95	allen[80%]
98	session beans	27.5 d	4/17/2000 9:28	5/24/2000 14:28		
99	design	1.25 d	4/17/2000 9:28	4/18/2000 11:28	89,84	sidharth[80%]
100	review	1.25 d	4/18/2000 11:28	4/19/2000 14:28	99	sidharth[80%]
101	code/unit test	2.5 d	5/22/2000 9:28	5/24/2000 14:28	100,85	rick[80%]
102	code unit test	2.5 d	4/19/2000 14:28	4/24/2000 9:28	100,86	peter[80%]
103		5 d	3/20/2000 8:00	3/24/2000 17:00		
104	Handheld Login and (User) Timeout	21.25 d	3/13/2000 8:00	4/11/2000 10:00		
105	investigation	8.75 d	3/13/2000 8:00	3/23/2000 15:00		
106	software evaluation / selection	1 d	3/13/2000 8:00	3/13/2000 17:00		cris[50%],AvantGo
107	testing	8.75 d	3/13/2000 8:00	3/23/2000 15:00		cris[80%]
108	design ui navigation	1 d	4/10/2000 10:00	4/11/2000 10:00	89	matt[80%]
109	HandHeld integration/development	7.63 d	3/23/2000 15:00	4/4/2000 11:00		
110	model / design	1.25 d	3/23/2000 15:00	3/24/2000 17:00	105	AvantGo
111	review	1.25 d	3/27/2000 8:00	3/28/2000 10:00	110	AvantGo
112	qa review	1 d	3/28/2000 10:00	3/29/2000 10:00	111	AvantGo
113	code/unit test	3.13 d	3/29/2000 10:00	4/3/2000 11:00	112	rick[80%]
114	delivery test	1 d	4/3/2000 11:00	4/4/2000 11:00	113	rick[80%]
115						
116	Resynchronization Timeout (Stale Data)	30.18 d	3/13/2000 8:00	4/24/2000 9:28		
117	investigation	6.25 d	3/13/2000 8:00	3/21/2000 10:00		
118	Evaluate options	2.5 d	3/13/2000 8:00	3/15/2000 12:00		cris[80%]
119	testing	3.75 d	3/15/2000 13:00	3/21/2000 10:00	118	cris[80%]
120	design ui navigation	3.75 d	4/11/2000 10:00	4/14/2000 17:00	108	matt[80%]
121	HandHeld integration/development	5 d	4/17/2000 9:28	4/24/2000 9:28		
122	design	1.25 d	4/17/2000 9:28	4/18/2000 11:28	95,21	phil[80%]
123	review	1.25 d	4/18/2000 11:28	4/19/2000 14:28	122	phil[80%]
124	qa review	1 d	4/19/2000 14:28	4/20/2000 14:28	123	qa
125	code/unit test	2.5 d	4/19/2000 14:28	4/24/2000 9:28	123	phil[80%]
126						
127	Task Visit Browse/View	16.43 d	4/17/2000 8:00	5/9/2000 11:28		
128	design ui navigation	2.5 d	4/17/2000 8:00	4/19/2000 12:00	120	matt[80%]
129	ui (JSP)	7 d	4/19/2000 13:00	4/28/2000 12:00		
130	design	2.5 d	4/19/2000 13:00	4/21/2000 17:00	128	matt[80%]
131	review	2 d	4/24/2000 8:00	4/25/2000 17:00	130	matt[40%]
132	qa review	2 d	4/24/2000 8:00	4/25/2000 17:00	130	matt[40%]
133	code/unit test	2.5 d	4/26/2000 8:00	4/28/2000 12:00	131,132	matt[80%]
134	session beans	13.75 d	4/19/2000 14:28	5/9/2000 11:28		
135	design	2.5 d	4/19/2000 14:28	4/24/2000 9:28	128,100	sidharth[80%]
136	review	1.25 d	4/24/2000 9:28	4/25/2000 11:28	135	sidharth[80%]
137	code unit test	10 d	4/25/2000 11:28	5/9/2000 11:28	136,102	peter[80%]
138						
139						
140	protocol loader	36.07 d	4/5/2000 14:28	5/25/2000 15:00		
141	protocol application model/design	6.25 d	4/5/2000 14:28	4/14/2000 16:28	61,10	kelly[80%]
142	review	1 d	4/14/2000 16:28	4/17/2000 16:28	141	qa
143	coding	11.25 d	5/4/2000 8:00	5/23/2000 10:00	141,142,73,11	kelly[80%]
144	unit test	2.5 d	5/23/2000 10:00	5/25/2000 15:00	143	kelly[80%]

145						
146	functional freeze	1 d	5/25/2000 15:00	5/26/2000 15:00	15	
147						
148	dev system test	5 d	5/29/2000 8:00	6/2/2000 17:00	146,12	
149	system test	5 d	5/29/2000 8:00	6/2/2000 17:00		sidharth[80%]
150	system test	5 d	5/29/2000 8:00	6/2/2000 17:00	33	matt[80%]
151	qa	2 d	5/29/2000 8:00	5/30/2000 17:00		qa[200%]
152						
153	qa	10 d	6/5/2000 8:00	6/23/2000 17:00	148	
154	bug fixing	10 d	6/5/2000 8:00	6/23/2000 17:00	148	matt[50%]
155	bug fixing	10 d	6/5/2000 8:00	6/23/2000 17:00	148	sidharth[25%]
156	bug fixing	10 d	6/5/2000 8:00	6/23/2000 17:00	101	rick[50%]
157						
158	qa release 1.0a	45.75 d	3/13/2000 8:00	5/15/2000 15:00		
159						
160	Dependencies	27.25 d	3/22/2000 13:00	4/28/2000 15:00		
161	finalized prd	1 d	3/22/2000 13:00	3/23/2000 12:00	169	arian
162	use cases	1 d	3/28/2000 10:00	3/29/2000 10:00	171	arian
163	hardware	1 d	4/27/2000 15:00	4/28/2000 15:00	181	sysa
164	testing tools	1 d	4/20/2000 15:00	4/21/2000 15:00	179	sysa
165						
166	process planning	6 d	3/13/2000 8:00	3/20/2000 17:00		jason,chris
167						
168	review cycle	9.75 d	3/21/2000 8:00	4/3/2000 15:00	166	
169	review prd	1.5 d	3/21/2000 8:00	3/22/2000 12:00		jason,chris
170	review protocol loader design	1.5 d	3/22/2000 13:00	3/23/2000 17:00	169	jason,chris
171	review use cases	2.25 d	3/24/2000 8:00	3/28/2000 10:00	170	jason,chris
172	review bus concept model	2.25 d	3/28/2000 10:00	3/30/2000 12:00	171	jason,chris
173	review qs user interface	2.25 d	3/30/2000 13:00	4/3/2000 15:00	172	jason,chris
174						
175	write/update test cases	7 d	4/3/2000 15:00	4/12/2000 15:00	168	jason,chris
176						
177	prepare test plan	2 d	4/12/2000 15:00	4/14/2000 15:00	175	jason,chris
178						
179	testing tools/reporting process	4 d	4/14/2000 15:00	4/20/2000 15:00	177	jason,chris
180						
181	setup test environment	5 d	4/20/2000 15:00	4/27/2000 15:00	179	jason,chris
182						
183	help with dev system test	2 d	4/27/2000 15:00	5/1/2000 15:00	181	jason,chris
184						
185	execute test plans	10 d	5/1/2000 15:00	5/15/2000 15:00	183	jason,chris
186						